



Rev 1: September 2018  
FSN Ref: FSN-18-001

FSCA Ref: FSCA-18-001

Date: 19-DEC-2018

**Urgent Field Safety Notice**  
**Allergan Textured Breast Implants and Tissue Expanders**

For Attention of\*:All Healthcare Professionals holding stock of Allergan textured breast implants and tissue expanders

Contact details of local representative (name, e-mail, telephone, address etc.) *
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<b>Arvind Patel, Arvind.Patel@Allergan.com, +44 (0)7983 166546, Allergan, Marlow International, Parkway, Marlow, Bucks, SL7 1YL, UK.</b>
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**Urgent Field Safety Notice (FSN)**

**Allergan Textured Breast Implants and Tissue Expanders**

Based on expiration of CE Mark, ANSM (France) requested Allergan perform a market withdrawal of all affected product in healthcare institutions


<b>1. Information on Affected Devices*</b>	
1	1. Device Type(s)*
.	Allergan textured breast implants are sterile, silicone gel-filled implantable devices designed to reconstruct or augment the breast. The implant may vary in shape, profile, volume, surface and shell thickness. Allergan textured tissue expanders are inflatable sterile devices implanted temporarily over a period of time to enlarge the tissue.
1	2. Commercial name(s)
.	See Appendix 1
1	3. Unique Device Identifier(s) (UDI-DI)
.	N/A
1	4. Primary clinical purpose of device(s)*
.	Allergan Breast Implants are used in augmentation and reconstruction mammoplasty. Allergan Tissue Expanders are intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage.
1	5. Device Model/Catalogue/part number(s)*
.	See Appendix 1
1	6. Software version
.	N/A
1	7. Affected serial or lot number range
.	All products as detailed in the Appendix
1	8. Associated devices
.	N/A

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	1. Description of the product problem*
.	Allergan textured breast implants and tissue expander CE mark certification expired on 16 December 2018. Allergan's Notified Body GMED, advised on 14 December 2018 that additional information was requested, and that the renewal was not completed at this time. The renewal review process is continuing, and Allergan continues to work with GMED to a satisfactory conclusion. ANSM (France) requested Allergan perform a market withdrawal of all affected product in healthcare institutions.
2	2. Hazard giving rise to the FSCA*
.	None. As noted by ANSM, no immediate risk for the health of women having the affected implants has been identified. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
2	3. Probability of problem arising
.	No problem has been identified. This is considered a precautionary activity conducted at request of ANSM. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
	4. Predicted risk to patient/users

2	Allergan is confident in the risk/benefit profile of our family of implant products. The safety profile of Allergan’s breast implants is supported by extensive pre-clinical and clinical data. There is more than a decade of successful U.S. and European clinical use as well as a large number of peer-reviewed and published studies. At this stage no immediate risk for the health of women having the affected implants has been identified and this is noted by ANSM. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
2	5. Further information to help characterise the problem
.	N/A
2	6. Background on Issue
.	Allergan’s breast implant portfolio is regulated in Europe by the French Notified Body, GMED. On a periodic basis, like all medical device manufacturers, Allergan is required to submit for renewal of its CE mark to manufacture and supply its devices, including its families of breast implants and tissue expanders. Allergan submitted its renewal for these products in August 2018. Allergan’s current certificates for its family of breast implant products were set to expire on December 16, 2018. Allergan was informed late Friday, December 14, 2018 by GMED that the routine review and renewal of our CE Mark for textured breast implants and tissue expanders has not been completed. As a result, the CE Mark for these products expired on December 16, 2018. Subsequently, Allergan was informed by ANSM, the French regulatory authority, that they are requiring the withdraw of any remaining supply in France. While Allergan is fully cooperating with the request, the Company stands behind the benefit/risk profile of our breast implant products. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
2	7. Other information relevant to FSCA
.	Allergan were requested by ANSM to perform a market withdrawal of all textured breast implants and tissue expanders. The action has been extended across the European region due to consistency of Competent Authority decisions.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device                        <input type="checkbox"/> Quarantine Device                        <input checked="" type="checkbox"/> Return Device                        <input type="checkbox"/> Destroy Device                 </p> <p> <input type="checkbox"/> On-site device modification/inspection                 </p> <p> <input type="checkbox"/> Follow patient management recommendations                 </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)                 </p> <p> <input type="checkbox"/> Other                      <input type="checkbox"/> None                 </p> <p>Provide further details of the action(s) identified.</p>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: center;">Immediately.</p>

3.	3. Particular considerations for: <span style="float: right;">Implantable device</span>  Is follow-up of patients or review of patients' previous results recommended? No  Based on the available scientific information, international health agencies are not recommending prophylactic removal or changes to current practice. As per standard of care, routine check-up will healthcare provider is recommended.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	<b>5. Action Being Taken by the Manufacturer</b>  <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None  Withdrawal of Allergan textured breast implants and tissue expanders. No action with regards to already implanted devices.	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item.                      Choose an item.	

<b>4. General Information*</b>	
4.	1. FSN Type* <span style="float: right;">New</span>
4.	2. For updated FSN, reference number and date of previous FSN <span style="float: right;">Provide reference and date of previous FSN if relevant</span>
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.
4.	4. Further advice or information already expected in follow-up FSN? * <span style="float: right;">No</span>
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc
4	6. Anticipated timescale for follow-up FSN <span style="float: right;">For provision of updated advice.</span>
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name <span style="float: right;"><b>Allergan</b></span>
	b. Address <span style="float: right;"><b>Marlow International, Parkway, Marlow, Bucks, SL7 1YL, United Kingdom</b></span>
	c. Website address <span style="float: right;"><b>www.allergan.com</b></span>
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: <span style="float: right;"><b>Appendix 1: Product ranges affected</b></span>
4.	10. Name/Signature <span style="float: right;"><b>Roisin Shanley. Associate Vice President, Quality Operations – Third Party, Commercial Quality</b></span>
	DocuSigned by:  A06D66AF43E94A9...

<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.

**Appendix 1 to FSCA/FSN-18-001**  
**Allergan Textured Breast Implants and Tissue Expanders**

<b>Product Name</b>	<b>Description</b>	<b>Catalogue Number/s</b>
<b>Natrelle 110</b>	BIOCELL Textured, INTRASHIEL, Truform Gel 1 Gel-filled, Round, Moderate Profile Mammary Implant	N-27-110091 N-27-110121 N-27-110151 N-27-110181 N-27-110211 N-27-110241 N-27-110271 N-27-110301 N-27-110331 N-27-110361 N-27-110391 N-27-110421 N-27-110451 N-27-110481 N-27-110511
<b>Natrelle 110 Soft Touch</b>	BIOCELL Textured, INTRASHIEL, Truform Gel 2 Gel-Filled, Round, Moderate Projection Mammary Implant	N-ST-110080 N-ST-110110 N-ST-110140 N-ST-110170 N-ST-110200 N-ST-110230 N-ST-110265 N-ST-110295 N-ST-110335 N-ST-110360 N-ST-110390 N-ST-110435 N-ST-110470 N-ST-110505 N-ST-110620 N-ST-110710 N-ST-110800
<b>Natrelle 120</b>	BIOCELL Textured, INTRASHIEL, Truform Gel 1 Gel-filled, Round, High Profile Mammary Implant	N-27-120181 N-27-120221 N-27-120261 N-27-120301 N-27-120341 N-27-120401 N-27-120451 N-27-120501 N-27-120551 N-27-120601 N-27-120651 N-27-120701* N-27-120751* N-27-120801*
<b>Natrelle 120 Soft Touch</b>	BIOCELL Textured, INTRASHIEL, Truform Gel 2 Gel-Filled, Round, Full Projection Mammary Implant	N-ST-120110* N-ST-120130* N-ST-120160 N-ST-120190 N-ST-120230 N-ST-120280

		N-ST-120310 N-ST-120365 N-ST-120410 N-ST-120460 N-ST-120525
<b>Natrelle 410</b> <b>FL, FM, FF, FX,</b> <b>ML, MM, MF,</b> <b>MX, LL, LM, LF,</b> <b>LX</b>	BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured, Truform Gel 3 Gel-filled, Anatomical Mammary Implants	N-27-FM095-155 N-27-FM100-180 N-27-FM105-205 N-27-FM110-235 N-27-FM115-270 N-27-FM120-310 N-27-FM125-350 N-27-FM130-395 N-27-FM135-440 N-27-FM140-500 N-27-FM145-550 N-27-FM150-605 N-27-FM155-670 N-27-MM095-135 N-27-MM100-160 N-27-MM105-185 N-27-MM110-215 N-27-MM115-245 N-27-MM120-280 N-27-MM125-320 N-27-MM130-360 N-27-MM135-400 N-27-MM140-450 N-27-MM145-500* N-27-MM150-555* N-27-ML095-110* N-27-ML100-125 N-27-ML105-150* N-27-ML110-170 N-27-ML115-195 N-27-ML120-220 N-27-ML125-250* N-27-ML130-285 N-27-ML135-320* N-27-ML140-360* N-27-ML145-390* N-27-ML150-440* N-27-FL095-120* N-27-FL100-140 N-27-FL105-170* N-27-FL110-190 N-27-FL115-220 N-27-FL120-250 N-27-FL125-285* N-27-FL130-320 N-27-FL135-360* N-27-FL140-400* N-27-FL145-440* N-27-FL150-495* N-27-FF095-160 N-27-FF100-185 N-27-FF105-220

		N-27-FF110-255 N-27-FF115-290 N-27-FF120-335 N-27-FF125-375 N-27-FF130-425 N-27-FF135-475 N-27-FF140-535 N-27-FF145-595 N-27-FF150-655 N-27-FF155-740 N-27-MF095-140 N-27-MF100-165 N-27-MF105-195 N-27-MF110-225 N-27-MF115-255 N-27-MF120-295 N-27-MF125-335 N-27-MF130-375 N-27-MF135-420 N-27-MF140-470 N-27-MF145-525 N-27-MF150-580 N-27-MF155-640 N-27-LL095-100* N-27-LL100-115* N-27-LL105-135 N-27-LL110-160* N-27-LL115-180 N-27-LL120-210 N-27-LL125-240 N-27-LL130-270* N-27-LL135-300 N-27-LL140-340* N-27-LL145-370* N-27-LL150-415* N-27-LL155-455* N-27-LM095-115* N-27-LM100-140 N-27-LM105-160* N-27-LM110-190 N-27-LM115-220 N-27-LM120-250 N-27-LM125-285* N-27-LM130-320 N-27-LM135-360* N-27-LM140-400* N-27-LM145-450* N-27-LM150-495* N-27-LM155-545* N-27-LF095-125 N-27-LF100-150 N-27-LF105-175 N-27-LF110-205 N-27-LF115-240 N-27-LF120-270 N-27-LF125-310 N-27-LF130-350*
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		N-27-LF135-390 N-27-LF140-440 N-27-LF145-490 N-27-LF150-540 N-27-LF155-595 N-27-LX095-145 N-27-LX100-175 N-27-LX105-195 N-27-LX110-225 N-27-LX115-255 N-27-LX120-290 N-27-LX125-330 N-27-LX130-365 N-27-LX135-405 N-27-LX140-455 N-27-LX145-515 N-27-LX150-570 N-27-LX155-625 N-27-LX160-685 N-27-MX095-165 N-27-MX100-195 N-27-MX105-225 N-27-MX110-255 N-27-MX115-290 N-27-MX120-325 N-27-MX125-370 N-27-MX130-410 N-27-MX135-445 N-27-MX140-520 N-27-MX145-550 N-27-MX150-620 N-27-MX155-685 N-27-MX160-765 N-27-FX095-185 N-27-FX100-215 N-27-FX105-245 N-27-FX110-280 N-27-FX115-315 N-27-FX120-360 N-27-FX125-410 N-27-FX130-450 N-27-FX135-495 N-27-FX140-560 N-27-FX145-615 N-27-FX150-690 N-27-FX155-775
<b>Natrelle 410</b> <b>Soft Touch FL,</b> <b>FM, FF, FX, ML,</b> <b>MM, MF, MX,</b> <b>LL, LM, LF, LX</b>	BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured, Truform™ Gel 2 Gel-filled, Anatomical Mammary Implants	N-ST-FM095-155 N-ST-FM100-180 N-ST-FM105-205 N-ST-FM110-235 N-ST-FM115-270 N-ST-FM120-310 N-ST-FM125-350 N-ST-FM130-395 N-ST-FM135-440 N-ST-FM140-500 N-ST-FM145-550

		N-ST-FM150-605 N-ST-FM155-670 N-ST-MM095-135 N-ST-MM100-160 N-ST-MM105-185 N-ST-MM110-215 N-ST-MM115-245 N-ST-MM120-280 N-ST-MM125-320 N-ST-MM130-360 N-ST-MM135-400 N-ST-MM140-450 N-ST-ML100-125 N-ST-ML110-170 N-ST-ML115-195 N-ST-ML120-220 N-ST-ML130-285 N-ST-FL100-140 N-ST-FL110-190 N-ST-FL115-220 N-ST-FL120-250 N-ST-FL130-320 N-ST-FF095-160 N-ST-FF100-185 N-ST-FF105-220 N-ST-FF110-255 N-ST-FF115-290 N-ST-FF120-335 N-ST-FF125-375 N-ST-FF130-425 N-ST-FF135-475 N-ST-FF140-535 N-ST-FF145-595 N-ST-FF150-655 N-ST-FF155-740 N-ST-MF095-140 N-ST-MF100-165 N-ST-MF105-195 N-ST-MF110-225 N-ST-MF115-255 N-ST-MF120-295 N-ST-MF125-335 N-ST-MF130-375 N-ST-MF135-420 N-ST-MF140-470 N-ST-MF145-525 N-ST-MF150-580 N-ST-MF155-640 N-ST-LL105-135 N-ST-LL115-180 N-ST-LL120-210 N-ST-LL125-240 N-ST-LL135-300 N-ST-LM100-140 N-ST-LM110-190 N-ST-LM115-220 N-ST-LM120-250
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		N-ST-LM130-320 N-ST-LF095-125 N-ST-LF100-150 N-ST-LF105-175 N-ST-LF110-205 N-ST-LF115-240 N-ST-LF120-270 N-ST-LF125-310 N-ST-LF130-350 N-ST-LF135-390 N-ST-LF140-440 N-ST-LF145-490 N-ST-LF150-540 N-ST-LF155-595 N-ST-LX095-145* N-ST-LX100-175* N-ST-LX105-195* N-ST-LX110-225* N-ST-LX115-255* N-ST-LX120-290* N-ST-LX125-330* N-ST-LX130-365* N-ST-LX135-405* N-ST-LX140-455* N-ST-LX145-515* N-ST-LX150-570* N-ST-LX155-625* N-ST-MX095-165* N-ST-MX100-195* N-ST-MX105-225* N-ST-MX110-255* N-ST-MX115-290* N-ST-MX120-325* N-ST-MX125-370* N-ST-MX130-410* N-ST-MX135-445* N-ST-MX140-520* N-ST-MX145-550* N-ST-MX150-620* N-ST-MX155-685* N-ST-FX095-185* N-ST-FX100-215* N-ST-FX105-245* N-ST-FX110-280* N-ST-FX115-315* N-ST-FX120-360* N-ST-FX125-410* N-ST-FX130-450* N-ST-FX135-495* N-ST-FX140-560* N-ST-FX145-615* N-ST-FX150-690* N-ST-FX155-775*
<b>Natrelle 510  Dual Gel  LX, MX, FX</b>	BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured,	N-510LX-130 N-510LX-155 N-510LX-185 N-510LX-205

	<p>Truform Dual Gel, Gel-filled, Anatomical Mammary Implant</p>	<p>N-510LX-230  N-510LX-275  N-510LX-305  N-510LX-330  N-510LX-365  N-510LX-425  N-510LX-475  N-510LX-530  N-510LX-575  N-510MX-145  N-510MX-175  N-510MX-200  N-510MX-220  N-510MX-245  N-510MX-290  N-510MX-335  N-510MX-360  N-510MX-385  N-510MX-445  N-510MX-490  N-510MX-550  N-510MX-600  N-510FX-165  N-510FX-190  N-510FX-210  N-510FX-250  N-510FX-280  N-510FX-310  N-510FX-350  N-510FX-400  N-510FX-435  N-510FX-495  N-510FX-545  N-510FX-595  N-510FX-630</p>
<p><b>Natrelle  Komuro  KML, KMM,  KLL, KLM</b></p>	<p>BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured,  Truform Gel 2 Gel-filled, Anatomical Mammary Implants</p>	<p>N-KML115  N-KML155  N-KML175  N-KML200  N-KML255  N-KMM145  N-KMM165  N-KMM195  N-KMM220  N-KMM250  N-KMM290  N-KMM325  N-KMM360  N-KMM405  N-KLL120  N-KLL160  N-KLL190  N-KLL215  N-KLL270  N-KLM125  N-KLM170  N-KLM200</p>

		N-KLM225 N-KLM290
<b>Natrelle Ritz Princess RML, RMM, RFL, RFM</b>	BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured, Truform™ Gel 1 Gel-filled, Anatomical Mammary Implants	N-RML115 N-RML155 N-RML175 N-RML200 N-RML255 N-RMM145 N-RMM165 N-RMM195 N-RMM220 N-RMM250 N-RMM290 N-RMM325 N-RMM360 N-RMM405 N-RFL125 N-RFL170 N-RFL200 N-RFL225 N-RFL290 N-RFM140 N-RFM160 N-RFM185 N-RFM210 N-RFM245 N-RFM280 N-RFM315 N-RFM355 N-RFM395 N-RFM450 N-RFM495 N-RFM545 N-RFM605
<b>Natrelle INSPIRA TRX, TRF, TRM, TRL, TRLP</b>	INTRASHIEL, BIOCELL Textured, Round, Truform Gel 1 Gel-filled, Mammary Implants	N- TRL110 N-TRL125 N- TRL140 N- TRL170 N- TRL200 N- TRL230 N- TRL260 N- TRL290 N- TRL320 N- TRL350 N- TRL380 N- TRL410 N- TRL460 N- TRL510 N- TRL560 N- TRL610 N-TRM140 N-TRM175 N-TRM195 N-TRM210 N-TRM240 N-TRM255 N-TRM275

		N-TRM295 N-TRM310 N-TRM330 N-TRM345 N-TRM360 N-TRM375 N-TRM405 N-TRM445 N-TRM485 N-TRM520 N-TRM560 N-TRM600 N-TRM640 N-TRM685 N-TRM755 N-TRF180 N-TRF200 N-TRF220 N-TRF240 N-TRF265 N-TRF295 N-TRF325 N-TRF335 N-TRF345 N-TRF365 N-TRF385 N-TRF415 N-TRF450 N-TRF485 N-TRF520 N-TRF560 N-TRF605 N-TRF650 N-TRF695 N-TRF745 N-TRF770 N-TRX205 N-TRX225 N-TRX255 N-TRX285 N-TRX310 N-TRX340 N-TRX375 N-TRX400 N-TRX420 N-TRX445 N-TRX470 N-TRX495 N-TRX525 N-TRX545 N-TRX560 N-TRX580 N-TRX615 N-TRX650 N-TRX700 N-TRX750 N-TRX800
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		N-TRLP125 N-TRLP145 N-TRLP165 N-TRLP190 N-TRLP205 N-TRLP220 N-TRLP235 N-TRLP250 N-TRLP265 N-TRLP280 N-TRLP300 N-TRLP320 N-TRLP340 N-TRLP360 N-TRLP400 N-TRLP440 N-TRLP490 N-TRLP540 N-TRLP590 N-TRLP640
<b>Natrelle  INSPIRA TSX,  TSF, TSM, TSL,  TSLP</b>	INTRASHIEL, BIOCELL Textured, Round, Truform Gel 2 Gel-filled, Mammary Implant	N-TSL110 N-TSL125 N-TSL140 N-TSL170 N-TSL200 N-TSL230 N-TSL260 N-TSL290 N-TSL320 N-TSL350 N-TSL380 N-TSL410 N-TSL460 N-TSL510 N-TSL560 N-TSL610 N-TSM140 N-TSM175 N-TSM195 N-TSM210 N-TSM240 N-TSM255 N-TSM275 N-TSM295 N-TSM310 N-TSM330 N-TSM345 N-TSM360 N-TSM375 N-TSM405 N-TSM445 N-TSM485 N-TSM520 N-TSM560 N-TSM600 N-TSM640 N-TSM685

		N-TSM755 N-TSF180 N-TSF200 N-TSF220 N-TSF240 N-TSF265 N-TSF295 N-TSF325 N-TSF335 N-TSF345 N-TSF365 N-TSF385 N-TSF415 N-TSF450 N-TSF485 N-TSF520 N-TSF560 N-TSF605 N-TSF650 N-TSF695 N-TSF745 N-TSF770 N-TSX205 N-TSX225 N-TSX255 N-TSX285 N-TSX310 N-TSX340 N-TSX375 N-TSX400 N-TSX420 N-TSX445 N-TSX470 N-TSX495 N-TSX525 N-TSX545 N-TSX560 N-TSX580 N-TSX615 N-TSX650 N-TSX700 N-TSX750 N-TSX800 N-TSLP125 N-TSLP145 N-TSLP165 N-TSLP190 N-TSLP205 N-TSLP220 N-TSLP235 N-TSLP250 N-TSLP265 N-TSLP280 N-TSLP300 N-TSLP320 N-TSLP340 N-TSLP360
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<b>McGhan 110</b>	BIOCELL Textured, INTRASHIEL, Truform Gel 1, Gel-filled, Round, Moderate Profile Mammary Implant	27-110091 27-110121 27-110151 27-110181 27-110211 27-110241 27-110271 27-110301 27-110331 27-110361 27-110391 27-110421 27-110451 27-110481 27-110511
<b>McGhan 120</b>	BIOCELL Textured, INTRASHIEL, Truform™ Gel 1, Gel-filled, Round, High Profile Mammary Implant	27-120181 27-120221 27-120261 27-120301 27-120341 27-120401 27-120451 27-120501 27-120551 27-120601 27-120651 27-120701 27-120751 27-120801
<b>McGhan™ 410 FL, FM, FF, ML, MM, MF, LL, LM, LF</b>	BioDIMENSIONAL™, INTRASHIEL, BIOCELL Textured, Truform Gel 3, Gel-filled, Anatomical Mammary Implants.	27-FM095-155 27-FM100-180 27-FM105-205 27-FM110-235 27-FM115-270 27-FM120-310 27-FM125-350 27-FM130-395 27-FM135-440 27-FM140-500 27-FM145-550 27-FM150-605 27-FM155-670 27-MM095-135 27-MM100-160 27-MM105-185 27-MM110-215 27-MM115-245 27-MM120-280 27-MM125-320 27-MM130-360

		27-MM135-400 27-MM140-450 27-MM145-500 27-MM150-555 27-ML095-110 27-ML100-125 27-ML105-150 27-ML110-170 27-ML115-195 27-ML120-220 27-ML125-250 27-ML130-285 27-ML135-320 27-ML140-360 27-ML145-390 27-ML150-440 27-FL095-120 27-FL100-140 27-FL105-170 27-FL110-190 27-FL115-220 27-FL120-250 27-FL125-285 27-FL130-320 27-FL135-360 27-FL140-400 27-FL145-440 27-FL150-495 27-FF095-160 27-FF100-185 27-FF105-220 27-FF110-255 27-FF115-290 27-FF120-335 27-FF125-375 27-FF130-425 27-FF135-475 27-FF140-535 27-FF145-595 27-FF150-655 27-FF155-740 27-MF095-140 27-MF100-165 27-MF105-195 27-MF110-225 27-MF115-255 27-MF120-295 27-MF125-335 27-MF130-375 27-MF135-420 27-MF140-470 27-MF145-525 27-MF150-580 27-MF155-640 27-LL095-100 27-LL100-115 27-LL105-135
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		27-LL110-160 27-LL115-180 27-LL120-210 27-LL125-240 27-LL130-270 27-LL135-300 27-LL140-340 27-LL145-370 27-LL150-415 27-LL155-455 27-LM095-115 27-LM100-140 27-LM105-160 27-LM110-190 27-LM115-220 27-LM120-250 27-LM125-285 27-LM130-320 27-LM135-360 27-LM140-400 27-LM145-450 27-LM150-495 27-LM155-545 27-LF095-125 27-LF100-150 27-LF105-175 27-LF110-205 27-LF115-240 27-LF120-270 27-LF125-310 27-LF130-350 27-LF135-390 27-LF140-440 27-LF145-490 27-LF150-540 27-LF155-595
<b>McGhan™ 410</b> <b><i>Soft Touch</i></b> <b>FL, FM, FF, ML,</b> <b>MM, MF, LL,</b> <b>LM, LF</b>	BioDIMENSIONAL, INTRASHIEL, BIOCELL Textured, Truform Gel 2, Gel-filled, Anatomical Mammary Implants.	ST-FM095-155 ST-FM100-180 ST-FM105-205 ST-FM110-235 ST-FM115-270 ST-FM120-310 ST-FM125-350 ST-FM130-395 ST-FM135-440 ST-FM140-500 ST-FM145-550 ST-FM150-605 ST-FM155-670 ST-MM100-160 ST-MM105-185 ST-MM110-215 ST-MM115-245 ST-MM120-280 ST-MM125-320 ST-MM130-360

		ST-MM135-400 ST-MM140-450 ST-ML100-125 ST-ML110-170 ST-ML115-195 ST-ML120-220 ST-ML130-285 ST-FL100-140 ST-FL110-190 ST-FL115-220 ST-FL120-250 ST-FL130-320 ST-FF095-160 ST-FF100-185 ST-FF105-220 ST-FF110-255 ST-FF115-290 ST-FF120-335 ST-FF125-375 ST-FF130-425 ST-FF135-475 ST-FF140-535 ST-FF145-595 ST-FF150-655 ST-FF155-740 ST-MF095-140 ST-MF100-165 ST-MF105-195 ST-MF110-225 ST-MF115-255 ST-MF120-295 ST-MF125-335 ST-MF130-375 ST-MF135-420 ST-MF140-470 ST-MF145-525 ST-MF150-580 ST-MF155-640 ST-LL105-135 ST-LL115-180 ST-LL120-210 ST-LL125-240 ST-LL135-300 ST-LM100-140 ST-LM110-190 ST-LM115-220 ST-LM120-250 ST-LM130-320 ST-LF095-125 ST-LF100-150 ST-LF105-175 ST-LF110-205 ST-LF115-240 ST-LF120-270 ST-LF125-310 ST-LF135-390 ST-LF140-440
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		ST-LF145-490 ST-LF150-540 ST-LF155-595
<b>CUI CML/BRST BCM</b>	Round, MicroCell Textured, DRIE, Gel-filled, Low Profile Mammary Implant	C-CML-080 C-CML-110 C-CML-140 C-CML-170 C-CML-200 C-CML-230 C-CML-265 C-CML-295 C-CML-335 C-CML-360 C-CML-390 C-CML-435 C-CML-470 C-CML-505 C-CML-620 C-CML-710 C-CML-800 BCM-080 BCM-110 BCM-140 BCM-170 BCM-200 BCM-230 BCM-265 BCM-295 BCM-335 BCM-360 BCM-390 BCM-435 BCM-470 BCM-505 BCM-620 BCM-710 BCM-800
<b>CUI CMH/BRST BCX</b>	Round, MicroCell Textured, DRIE, Gel-filled, High Profile Mammary Implant	C-CMH-110* C-CMH-130* C-CMH-160 C-CMH-190 C-CMH-230 C-CMH-280 C-CMH-310 C-CMH-365 C-CMH-410 C-CMH-460 C-CMH-525 BCX-160 BCX-190 BCX-230 BCX-280 BCX-310 BCX-365 BCX-410 BCX-460 BCX-525

<p><b>CUI MLP/BRST BRM</b></p>	<p>Round, MicroCell Textured, DRIE, Gel-filled, Low Profile Mammary Implant</p>	<p>C-MLP-110 C-MLP-140 C-MLP-170 C-MLP-200 C-MLP-230 C-MLP-260 C-MLP-290 C-MLP-320 C-MLP-350 C-MLP-380 C-MLP-435 C-MLP-470 C-MLP-505 BRM-110 BRM-140 BRM-170 BRM-200 BRM-230 BRM-260 BRM-290 BRM-320 BRM-350 BRM-380 BRM-435 BRM-470 BRM-505</p>
<p><b>CUI MHP/BRST BRF</b></p>	<p>Round, MicroCell Textured, DRIE, Gel-filled, High Profile Mammary Implant</p>	<p>C-MHP-100 C-MHP-130 C-MHP-160 C-MHP-190 C-MHP-230 C-MHP-260 C-MHP-300 C-MHP-340 C-MHP-380 C-MHP-410 C-MHP-460 C-MHP-525 BRF-100 BRF-130 BRF-160 BRF-190 BRF-230 BRF-260 BRF-300 BRF-340 BRF-380 BRF-410 BRF-460 BRF-525</p>
<p><b>CUI CMM</b></p>	<p>Anatomical, Moderate Height, Moderate Projection, MicroCell Textured, DRIE, Silicone Gel-filled Breast Implant</p>	<p>C-CMM-160 C-CMM-185 C-CMM-215 C-CMM-245 C-CMM-280 C-CMM-320 C-CMM-360</p>

		C-CMM-400 C-CMM-450
<b>CUI CFM</b>	Anatomical, Full Height, Moderate Projection, MicroCell Textured, DRIE, Silicone Gel-filled Breast Implant	C-CFM-155 C-CFM-180 C-CFM-205 C-CFM-235 C-CFM-270 C-CFM-310 C-CFM-350 C-CFM-395 C-CFM-440 C-CFM-500
<b>BRST CHP</b>	Round, MicroCell Textured DRIE, High Profile, Cohesive Gel-filled, Mammary Implant	CHP-220 CHP-240 CHP-265 CHP-325 CHP-345 CHP-385 CHP-450 CHP-520 CHP-560 CHP-605
<b>BRST CLP</b>	Round, MicroCell Textured DRIE, Low Profile, Cohesive Gel-filled, Mammary Implant	CLP-145 CLP-165 CLP-190 CLP-220 CLP-250 CLP-280 CLP-320 CLP-360 CLP-400 CLP-440
<b>BRST CMP</b>	Round, MicroCell Textured DRIE, Moderate Profile, Cohesive Gel-filled, Mammary Implant	CMP-175 CMP-210 CMP-240 CMP-275 CMP-310 CMP-345 CMP-375 CMP-445 CMP-485 CMP-520
<b>BRST CXP</b>	Round, MicroCell Textured DRIE, Extra High Profile, Cohesive Gel-filled, Mammary Implant.	CXP-255 CXP-285 CXP-310 CXP-375 CXP-420 CXP-470 CXP-525 CXP-560 CXP-615 CXP-700
<b>BRST RHP</b>	Round, MicroCell Textured DRIE, High Profile, Responsive Gel-filled, Mammary Implant	RHP-220 RHP-240 RHP-265 RHP-325

		RHP-345 RHP-385 RHP-450 RHP-520 RHP-560 RHP-605
<b>BRST RLP</b>	Round, MicroCell Textured DRIE, Low Profile, Responsive Gel-filled, Mammary Implant	RLP-145 RLP-165 RLP-190 RLP-220 RLP-250 RLP-280 RLP-320 RLP-360 RLP-400 RLP-440
<b>BRST RMP</b>	Round, MicroCell Textured DRIE, Moderate Profile, Responsive Gel-filled, Mammary Implant	RMP-175 RMP-210 RMP-240 RMP-275 RMP-310 RMP-345 RMP-375 RMP-445 RMP-485 RMP-520
<b>Natrelle 150 Full Height</b>	BioDIMENSIONAL Silicone Gel with Adjustable Saline-Fill Inner Lumen Expandable Breast Implant, Mini Remote Port, BIOCELL Textured Shell, INTRASHIEL Barrier Shell, Anatomical Shape	N-27-150231 N-27-150281 N-27-150351 N-27-150431 N-27-150521 N-27-150621 N-27-150721
<b>Natrelle 150 Short Height</b>	BioDIMENSIONAL Silicone Gel with Adjustable Saline-Fill Inner Lumen Expandable Breast Implant, Mini Remote Port, BIOCELL Textured Shell, INTRASHIEL Barrier Shell, Anatomical Shape	N-27-150136 N-27-150166 N-27-150236 N-27-150296 N-27-150386 N-27-150496 N-27-150626
<b>CUI XML</b>	Round Expandable, MicroCell Textured Shell, DRIE, Low Profile Breast Implant	C-XML-180 C-XML-240 C-XML-300 C-XML-360 C-XML-420 C-XML-510 C-XML-600 C-XML-700



<b>Natrelle™ 168</b>	BIOCELL™, Textured, Saline-Filled Breast Implant, Anterior Diaphragm Valve, RTV Shell, Round, Moderate Profile.	N-27-168121 N-27-168151 N-27-168181 N-27-168211 N-27-168241 N-27-168271 N-27-168301 N-27-168331 N-27-168361 N-27-168391 N-27-168421 N-27-168451 N-27-168481 N-27-168511
<b>Natrelle™ 363</b>	BioDIMENSIONAL™, Saline-Filled Breast Implant, Anterior Diaphragm Valve, BIOCELL™ Textured RTV Shell, Short Height, Anatomical Shape.	N-27-363231 N-27-363311 N-27-363391 N-27-363511 N-27-363651
<b>Natrelle™ 468</b>	BioDIMENSIONAL™, Saline-Filled Breast Implant, Anterior Diaphragm Valve, BIOCELL™ Textured RTV Shell, Anatomical Shape.	N-27-468196 N-27-468231 N-27-468271 N-27-468301 N-27-468351 N-27-468381 N-27-468451 N-27-468496 N-27-468561 N-27-468621
<b>CUI RTT</b>	MicroCell™ RTV Textured, Saline-Filled Breast Implant, Anterior Diaphragm Valve, Round.	C-RTT-2090 C-RTT-2120 C-RTT-2150 C-RTT-2180 C-RTT-2210 C-RTT-2240 C-RTT-2270 C-RTT-2300 C-RTT-2330 C-RTT-2360 C-RTT-2390 C-RTT-2420 C-RTT-2450 C-RTT-2480 C-RTT-2510
<b>Natrelle 133FV</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Full Height, Variable Projection	N-67-133FV11 N-67-133FV12 N-67-133FV13 N-67-133FV14 N-67-133FV15 N-67-133FV16
<b>Natrelle 133MV</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable Projection	N-67-133MV11 N-67-133MV12 N-67-133MV13 N-67-133MV14 N-67-133MV15 N-67-133MV16

<b>Natrelle 133LV</b>	BioDIMENSIONAL Croissant Shaped Tissue Expander for 2-stage breast reconstruction with BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Low Height, Variable Projection	N-67-133LV11 N-67-133LV12 N-67-133LV13 N-67-133LV14 N-67-133LV15 N-67-133LV16
<b>Natrelle 133FX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Full Height, Variable (extra full) Projection	N-67-133FX11 N-67-133FX12 N-67-133FX13 N-67-133FX14 N-67-133FX15 N-67-133FX16
<b>Natrelle 133MX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable (extra full) Projection	N-67-133MX11 N-67-133MX12 N-67-133MX13 N-67-133MX14 N-67-133MX15 N-67-133MX16
<b>Natrelle 133SX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Short Height, Variable (extra full) Projection	N-67-133SX11 N-67-133SX12 N-67-133SX13 N-67-133SX14 N-67-133SX15 N-67-133SX16
<b>Natrelle 133SV</b>	BioDIMENSIONAL Semi Circular Tissue Expander for 2-stage breast reconstruction with BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Short Height, Variable Projection	N-67-133SV11 N-67-133SV12 N-67-133SV13 N-67-133SV14 N-67-133SV15 N-67-133SV16
<b>Natrelle T-133FV</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell, MAGNA-SITE Integral Injection Site, Full Height, Variable Projection	N-67-T-133FV11 N-67-T-133FV12 N-67- T-133FV13 N-67- T-133FV14 N-67- T-133FV15 N-67- T-133FV16
<b>Natrelle T-133MV</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Moderate Height, Variable Projection	N-67-T-133MV11 N-67-T-133MV12 N-67-T-133MV13 N-67-T-133MV14 N-67-T-133MV15 N-67-T-133MV16
<b>Natrelle T-133LV</b>	BioDIMENSIONAL Croissant Shaped Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Low Height, Variable Projection	N-67-T-133LV11 N-67-T-133LV12 N-67-T-133LV13 N-67-T-133LV14 N-67-T-133LV15 N-67-T-133LV16
<b>Natrelle T-133FX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Full Height, Variable (extra full) Projection	N-67-T-133FX11 N-67-T-133FX12 N-67-T-133FX13 N-67-T-133FX14 N-67-T-133FX15 N-67-T-133FX16
<b>Natrelle T-133MX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction	N-67-T-133MX11 N-67-T-133MX12

	with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Moderate Height, Variable (extra full) Projection	N-67-T-133MX13 N-67-T-133MX14 N-67-T-133MX15 N-67-T-133MX16
<b>Natrelle T-133SX</b>	BioDIMENSIONAL Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Short Height, Variable (extra full) Projection	N-67-T-133SX11 N-67-T-133SX12 N-67-T-133SX13 N-67-T-133SX14 N-67-T-133SX15 N-67-T-133SX16
<b>Natrelle T-133SV</b>	BioDIMENSIONAL Semi Circular Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL Textured shell and MAGNA-SITE Integral Injection Site, Short Height, Variable Projection	N-67-T-133SV11 N-67-T-133SV12 N-67-T-133SV13 N-67-T-133SV14 N-67-T-133SV15 N-67-T-133SV16
<b>Natrelle™ Plus 133P-FV</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Full Height, Variable Projection	N-67-T-133P-FV11 N-67-T-133P-FV12 N-67-T-133P-FV13 N-67-T-133P-FV14 N-67-T-133P-FV15 N-67-T-133P-FV16
<b>Natrelle™ Plus 133P-MV</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable Projection	N-67-T-133P-MV11 N-67-T-133P-MV12 N-67-T-133P-MV13 N-67-T-133P-MV14 N-67-T-133P-MV15 N-67-T-133P-MV16
<b>Natrelle™ Plus 133P-LV</b>	BioDIMENSIONAL™ Croissant Shaped Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Low Height, Variable Projection	N-67-T-133P-LV11 N-67-T-133P-LV12 N-67-T-133P-LV13 N-67-T-133P-LV14 N-67-T-133P-LV15 N-67-T-133P-LV16
<b>Natrelle™ Plus 133P-FX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Full Height, Variable (extra full) Projection	N-67-T-133P-FX11 N-67-T-133P-FX12 N-67-T-133P-FX13 N-67-T-133P-FX14 N-67-T-133P-FX15 N-67-T-133P-FX16
<b>Natrelle™ Plus 133P-MX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable (extra full) Projection	N-67-T-133P-MX11 N-67-T-133P-MX12 N-67-T-133P-MX13 N-67-T-133P-MX14 N-67-T-133P-MX15 N-67-T-133P-MX16
<b>Natrelle™ Plus 133P-SX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Short Height, Variable (extra full) Projection	N-67-T-133P-SX11 N-67-T-133P-SX12 N-67-T-133P-SX13 N-67-T-133P-SX14 N-67-T-133P-SX15 N-67-T-133P-SX16
<b>Natrelle™ Plus 133P-SV</b>	BioDIMENSIONAL™ Semi Circular Tissue Expander for 2-stage breast reconstruction with BIOCELL™ Textured shell and MAGNA-	N-67-T-133P-SV11 N-67-T-133P-SV12 N-67-T-133P-SV13 N-67-T-133P-SV14

	SITE™ Integral Injection Site, Short Height, Variable Projection	N-67-T-133P-SV15 N-67-T-133P-SV16
<b>Natrelle™ Plus T-133P-FV</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell, MAGNA-SITE™ Integral Injection Site, Full Height, Variable Projection	N-67-133P-FV11 N-67-133P-FV12 N-67-133P-FV13 N-67-133P-FV14 N-67-133P-FV15 N-67-133P-FV16
<b>Natrelle™ Plus T-133P-MV</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable Projection.	N-67-133P-MV11 N-67-133P-MV12 N-67-133P-MV13 N-67-133P-MV14 N-67-133P-MV15 N-67-133P-MV16
<b>Natrelle™ Plus T-133P-LV</b>	BioDIMENSIONAL™ Croissant Shaped Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Low Height, Variable Projection.	N-67-133P-LV11 N-67-133P-LV12 N-67-133P-LV13 N-67-133P-LV14 N-67-133P-LV15 N-67-133P-LV16
<b>Natrelle™ Plus T-133P-FX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Full Height, Variable (extra full) Projection.	N-67-133P-FX11 N-67-133P-FX12 N-67-133P-FX13 N-67-133P-FX14 N-67-133P-FX15 N-67-133P-FX16
<b>Natrelle™ Plus T-133P-MX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Moderate Height, Variable (extra full) Projection.	N-67-133P-MX11 N-67-133P-MX12 N-67-133P-MX13 N-67-133P-MX14 N-67-133P-MX15 N-67-133P-MX-16
<b>Natrelle™ Plus T-133P-SX</b>	BioDIMENSIONAL™ Anatomical Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Short Height, Variable (extra full) Projection.	N-67-133P-SX11 N-67-133P-SX12 N-67-133P-SX13 N-67-133P-SX14 N-67-133P-SX15 N-67-133P-SX16
<b>Natrelle™ Plus T-133P-SV</b>	BioDIMENSIONAL™ Semi Circular Tissue Expander for 2-stage breast reconstruction with Suture Tabs, BIOCELL™ Textured shell and MAGNA-SITE™ Integral Injection Site, Short Height, Variable Projection.	N-67-133P-SV11 N-67-133P-SV12 N-67-133P-SV13 N-67-133P-SV14 N-67-133P-SV15 N-67-133P-SV16