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Teleflex Medical
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Phone: +44 (0)1494 532761
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11th August 2009

Urgent
Field Safety Notice

Commercial Name of Affected Product:	**SHERI-I-SWIV** **SHER-I-BRONCH**
Type of action:	**PRODUCT RECALL**

Please pass this notice to the Risk Management Division or Director of Purchasing for your institution

Dear Customer,

1. Details on affected devices

Teleflex Medical has issued a voluntary recall for the specific catalog numbers and date range of the **SHER-I-SWIV and SHER-I-BRONCH** as shown in the table below. Affected batch numbers are listed in Appendix A of this field safety notice.

Catalog Number	Description	Date Range
5-15301	Sher-I-Swiv	May 1, 2004 through May 31, 2009
5-15401	Sher-I-Swiv F/O	
5-16028	ET Tube, Sher-I-Bronch LS, 28FR	
5-16035	ET Tube, Sher-I-Bronch LS, 35FR	
5-16037	ET Tube, Sher-I-Bronch LS, 37FR	
5-16039	ET Tube, Sher-I-Bronch LS, 39FR	
5-16041	ET Tube, Sher-I-Bronch LS, 41FR	
5-16128	ET Tube, Sher-I-Bronch RS, 28FR	
5-16135	ET Tube, Sher-I-Bronch RS, 35FR	
5-16137	ET Tube, Sher-I-Bronch RS, 37FR	
5-16139	ET Tube, Sher-I-Bronch RS, 39FR	
5-16141	ET Tube, Sher-I-Bronch RS, 41FR	
5-16142	Sher-I-Bronch Accessory Pack	
V5-16035	EB Tube, Sher-I-Bronch, LS, 35FR, Nova Plus	
V5-16037	EB Tube, Sher-I-Bronch, LS, 37FR, Nova Plus	

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Catalog Number	Description	Date Range
V5-16039	EB Tube, Sher-I-Bronch, LS, 39FR, Nova Plus	May 1, 2004 through May 31, 2009
V5-16041	EB Tube, Sher-I-Bronch, LS, 41FR, Nova Plus	

2. Description of the problem

Teleflex Medical has determined that the tether attaching to the double swivel cap may partially or completely break at the attachment points. The broken tether may lodge inside the dual swivel tubing or body during shipment to the end user, resulting in the potential for the accidental aspiration of the tether into the patient's lungs.

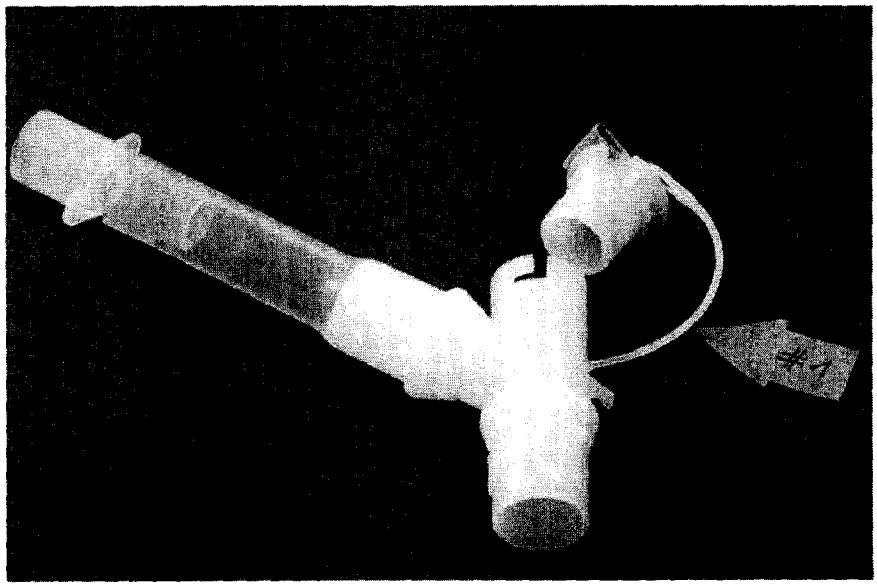

Figure 1
SHER-I-BRONCH Swivel Connector
(The tether is identified by the tag #1 in the image above)

3. Advise on action to be taken by Medical Staff

Our records indicate you have received product included in the scope of this recall. We are notifying our Customers to take the following action:

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RECALL INSTRUCTIONS:

Instructions for Hospitals/Medical Staff/Customers

1. **Check your stock for the products included within the scope of this recall. Cease use and distribution, and quarantine all affected product immediately.**

2. **Contact Teleflex Medical Customer Service Department at 01494 532761 for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the attached Recall Acknowledgement & Stock Status Form.**

3. **Complete the enclosed Recall Acknowledgement & Stock Status Form and immediately fax back to Teleflex Medical, Fax number: 01494 524650, Attn: Customer Service. This will allow us to document your receipt of this letter and the amount of product you have on hand for return.**

4. **Return any affected product freight collect, along with the original completed Recall Acknowledgement & Stock Status Form to the following:**

   Hélène Sauvage
   Stirling Road
   Cressex Business Park
   High Wycombe
   HP12 3ST
   England
   Phone: +44 (0)1494 532761
   Fax: +44 (0)1494 524650
   E-mail: orders.uk@teleflexmedical.com

   Note: Teleflex Medical can provide either replacement product at no charge or credit your account when the product is returned. Please indicate which you desire on the Recall Acknowledgement & Stock Status Form.

Instructions for Distributors

If you are a distributor, communicate this recall notice to your customers who received product within the scope of this recall by providing a copy of this recall notification to them. Also provide a copy of the Acknowledgement Form. This form should be completed in its entirety, signed and returned to you (the Distributor). As a Distributor, it is your responsibility to provide Teleflex Medical with a certification that all of your consignees have been contacted under this recall.

If you have any other questions, please feel free to contact your local sales representative or the Teleflex Medical Customer Service available at: 01494 532761

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5. Teleflex Medical Action

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

6. Transmission of this Field Safety Notice

This notice should be passed on all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

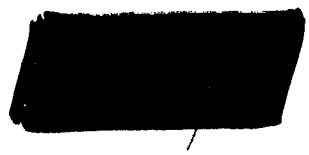
7. Contact reference person

Should you require any further information or support concerning this issue, please contact:

Hélène Sauvage
Phone 01494 532761
Fax 01494 524650
E-mail: orders.uk@teleflexmedical.com

This recall is voluntary and all affected competent authorities have been advised of this Field Safety Corrective Action.

Teleflex Medical is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service at **01494 532761.**



[redacted]
VP Quality Assurance & Regulatory Affairs, EMEA

Attachments:
Appendix A: List of batches affected by this Field Safety Corrective Action
Appendix B: Recall Acknowledgement Form & Stock Status Form

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APPENDIX A
URGENT FIELD SAFETY NOTICE
SHER-I-SWIV and SHER-I-BRONCH
AFFECTED PRODUCT CODES & BATCH NUMBERS

Product code	Product Description	Affected Lot Numbers
5-15301	Sher-I-Swiv	1132962, 1135424, 1136773, 1169645, 1173522, 1178399, 1188200, 1186993, 1194489,1201020, 1212344, 1258338, 1269036, 01L0700243, 01A0800245, 01C0800104, 01E0800341, 01F0800283, 01F0800354, 01L0800005, 01M0800250, 01A0900036
5-15401	Sher-I-Swiv F/O	1152620, 1153518, 1153626, 1155031, 1156400, 1156986, 1157666, 1160298, 1164076, 1169644, 1168080, 1172007, 1173521, 1182297, 1186762, 1193750, 1195118, 1276554, X1198365, X1198635, 01B0800103, 01F0800284, 01G0800362, 01H0800175, 01J0800015, 01A0900367, 01D0900087
5-16028	ET Tube, Sher-I-Bronch LS, 28FR	1163823, 1206612, 1223205, 1231357, 1244556, 1252502, X1240217, 01F0800193, 01F0800289, 01L0800169
5-16035	ET Tube, Sher-I-Bronch LS, 35FR	1138516, 1140269, 1142027, 1143591, 1143610, 1143775, 1145101, 1145384, 1146183, 1148986, 1149631, 1150442, 1155626, 1157564, 1164122, 1165476, 1169574, 1170554, 1174447, 1178483, 1183447, 1185568, 1189653, 1194375, 1195121, 1201934, 1209310, 1210115, 1211569, 1216011, 1235840, 1238472, 1241371, 1241505, 1243845, 1244254, 1252504, 1258990, 1261906, 1263704, 1264908, 1263863, 1268698, 1271774, 1271775, 1274789, 1279285, 1280242, X1148352, X1158229, 01L0700413, 01L0700299, 01A0800102, 01B0800270, 01C0800185, 01D0800066, 01D0800257, 01F0800056, 01F0800191, 01F0800288, 01H0800056, 01H0800171, 01J0800458, 01J0800459, 01K0800275, 01K0800276, 01L0800292, 01L0800293, 01M0800058, 01M0800059, 01B0900229, 01C0900084, 01C0900345, 01D0900001
5-16037	ET Tube, Sher-I-Bronch LS, 37FR	1134390, 1134620, 1135985, 1136800, 1137694, 1139466, 1140266, 1141630, 1143594, 1143781, 1145079, 1145383, 1146242, 1147855, 1149630, 1150443, 1152635, 1153621, 1158924, 1159137, 1165584, 1167116, 1170556, 1175203, 1176065, 1179985, 1183449, 1186327, 1188199, 1189032, 1190949, 1193073, 1193746, 1199353, 1200164, 1201040, 1212368, 1218623, 1224867, 1229983, 1230412, 1231358, 1232761, 1236305, 1237250, 1238139, 1239644, 1240215, 1245593, 1251482, 1252221, 1255615, 1263705, 1264907, 1266782, 1270819, 1273893, 1273896, 1277744, 1280243, 1280705, 1281123, X1179890, X1180634, X1181534, X1238185, 01L0700055, 01L0700056, 01L0700225, 01L0700300, 01M0700001, 01B0800021, 01B0800195, 01B0800356, 01C0800106, 01C0800186, 01D0800215, 01E0800063, 01E0800232, 01E0800328, 01F0800290, 01F0800355, 01G0800319, 01H0800403, 01J0800074, 01J0800149, 01J0800222, 01J0800223, 01K0800011, 01K0800038, 01K0800147, 01L0800067, 01L0800068, 01L0800523, 01L0800524, 01M0800206, 01M0800272, 01M0800317, 01A0900043, 01A0900125, 01C0900361

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Product code	Product Description	Affected Lot Numbers
5-16039	ET Tube, Sher-I-Bronch LS, 39FR	1133790, 1135142, 1136768, 1139464, 1140267, 1142034, 1152984, 1156320, 1161353, 1162526, 1164081, 1167117, 1170557, 1171390, 1173367, 1173518, 1179984, 1184132, 1184133, 1186959, 1191585, 1198623, 1202821, 1205971, 1206609, 1207350, 1215046, 1215133, 1220397, 1225847, 1234644, 1238473, 1239645, 1240216, 1246654, 1252180, 1255614, 1263866, 1266009, 1270820, 1270821, 1271773, 1273897, 1273898, 1281125, 01K0700058, 01K0700359, 01L0700149, 01B0800196, 01B0800357, 01C0800351, 01D0800068, 01E0800133, 01E0800397, 01E0800398, 01G0800370, 01J0800328, 01J0800329, 01K0800503, 01K0800504, 01A0900044, 01B0900081, 01B0900404
5-16041	ET Tube, Sher-I-Bronch LS, 41FR	1144302, 1161067, 1167582, 1172627, 1175218, 1185570, 1190334, 1193744, 1197170, 1215132, 1228699, 1232762, 1233315, 1274787, 1280244, X1240255, 01K0700159, 01B0800358, 01E0800327, 01H0800058, 01H0800170, 01M0800060
5-16128	ET Tube, Sher-I-Bronch RS, 28FR	1169573, 1183453, 1186960, 1197168, 1205969, 1219532, 1233316, 1247807, 1256372, X1177389, 01K0800372, 01D0900068
5-16135	ET Tube, Sher-I-Bronch RS, 35FR	1138507, 1141035, 1145947, 1146249, 1148606, 1151231, 1152184, 1157033, 1169746, 1174454, 1176787, 1186981, 1190223, 1193745, 1198626, 1242901, 1256154, 1274788, 1279286, 1281124, 01K0700161, 01L0700414, 01A0800144, 01H0800280, 01K0800146
5-16137	ET Tube, Sher-I-Bronch RS, 37FR	1137695, 1140908, 1142035, 1144366, 1147062, 1148460, 1151236, 1152636, 1153628, 1154943, 1182363, 1187556, 1190332, 1192253, 1198625, 1241506, 1241616, 1244557, 1270823, 1278941, 1279287, X1158231, X1184238, X1189657, X49036, 01K0700357, 01L0700150, 01L0700226, 01E0800064, 01E0800132, 01E0800400, 01F0800057, 01F0800356, 01G0800167, 01K0800123, 01K0800384, 01L0800167
5-16139	ET Tube, Sher-I-Bronch RS, 39FR	1136908, 1141067, 1142803, 1155672, 1162104, 1163822, 1172148, 1175219, 1179997, 1183450, 1190333, 1192254, 1219531, 1247271, 1270822, 1273899, 01K0700060, 01K0700258, 01C0800327, 01E0800399, 01F0800192, 01K0800385, 01A0900218
5-16141	ET Tube, Sher-I-Bronch RS, 41FR	1141964, 1162103, 1172149, 1185571, 1197167, X1176100, 01C0800328
5-16142	Sher-I-Bronch Accessory Pack	1162530, 1167118, 1169739, 1169740, 1190331, 1200165, 1207348
V5-16035	EB Tube, Sher-I-Bronch, LS, 35FR, Nova Plus	1140268, 1140907, 1170555, 1178484, 1183448, 1194376, 1201935, 1208297, 1244546, 1275365, 01A0800182, 01D0800258, 01H0800057, 01H0800402
V5-16037	EB Tube, Sher-I-Bronch, LS, 37FR, Nova Plus	1145385, 1153622, 1158906, 1160679, 1163824, 1176066, 1182302, 1185569, 1190950, 1193074, 1199354, 1236306, 1246651, 1271778, 1278921, 1280706, 01K0700358, 01B0800201, 01C0800187, 01G0800445, 01J0800075, 01A0900206
V5-16039	EB Tube, Sher-I-Bronch, LS, 39FR, Nova Plus	1133751, 1152985, 1161068, 1164080, 1170555, 1176067, 1184133, 1191586, 1197169, 1198624, 1214179, 1215134, 1234645, 1266007, 166785, 1268697, 1271779, 01B0800049, 01B0800202, 01C0800352, 01G0800444, 01A0900241

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Product code	Product Description	Affected Lot Numbers
V5-16041	EB Tube, Sher-I-Bronch, LS, 41FR, Nova Plus	1167165, 1178485, 1197171, 1205970, 01K0700160, 01K0800041

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APPENDIX B

RECALL ACKNOWLEDGEMENT AND STOCK STATUS FORM

FAX TO: Customer Service FAX: +44 (0)1494 524650

Immediate Attention Requested - Field Safety Notice – SHER-I-SWIV and SHER-I-BRONCH

Please check the appropriate box and return this form by Fax to the number above.

☐ We have no inventory within the scope of this recall.	☐ We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. When the product is received by Teleflex Medical, please (select one):
☐ Send replacement product, or	☐ Send similar product for replacement, or ☐ Credit our account.
	Return Authorization Number:

Product No.		**Product No.**		**Product No.**		**Product No.**		**Product No.**	
Lot #	Qty (ea)	Lot #	Qty (ea)	Lot #	Qty (ea)	Lot #	Qty (ea)	Lot #	Qty (ea)

Complete this Acknowledgement Form and immediately fax to Teleflex Medical at the number given above.

Print Name/Title

Date

Institution Name

Signature

Telephone Number

Address

City, State, Zip Code