Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

See Related Information[21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1794-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm) Standard Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4500; Material Number: M004PM45000; Serial numbers: 16521554, 16538010, 16573561, 16615973, 16744972, 16744973, 16744974, 16744975, 16872127, 16872836. Expiry Dates: May 7, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units - all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

See Related Information [21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1795-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm); Large Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4500K2; Material Number: M004PM45000K20; Serial numbers: 16560406, 16560408, 16573562, 16573563, 16573564, 16599366, 16606148, 16615974, 16615975, 16623756, 16743274, 16743275, 16743276, 16757632, 16757633, 16757634, 16757635, 16757636, 16757637, 16757638, 16757639, 16757781, 16757782, 16872835. Expiry Dates: May 11, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units total all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

See Related Information[21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1796-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm); Asymmetric Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4500N4; Material Number: M004PM45000N40; Serial numbers: 16521557, 16615976, 16623754, 16623755, 16736927, 16739588, 16743271, 16872124. Expiry Dates: May 11, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units total all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

See Related Information[21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1797-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm) Standard Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4790; Material Number: M004PM47900; Serial numbers: 16538009, 16743272, 16743273, 16872937 Expiry Dates: May 11, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units total all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

See Related Information[21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1798-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm) Large Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4790K2; Material Number: M004PM47900K2; Serial numbers: 16739673, 16739674, 16739675, 16739676, 16739677, 16739678, 16739679, 16739860, 16872121, 16872935 Expiry Dates: May 11, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units total all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

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Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

See Related Information[21]

Date Posted	June 16, 2014
Recall Status[1]	Open
Recall Number	Z-1799-2014
Recall Event ID	68373[22]
Product	IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm) Asymmetric Curve. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.
Code Information	Catalog Number: PM4790N4; Material Number: M004PM47900N4; Serial numbers: 16743269, 16872007; Expiry Dates: May 11, 2014 to January 13, 2017
Recalling Firm/ Manufacturer	Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530
For Additional Information Contact	Brent Hathcock 510-440-7700
Manufacturer Reason for Recall	Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.
Action	Customers were informed of the recall via overnight letter sent on May 15, 2014.
Quantity in Commerce	968 units - all models
Distribution	Nationwide Distribution.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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Class 2 Device Recall TAMPA CATHETER 5 French 33 cm.

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Class 2 Recall
TAMPA CATHETER 5 French 33 cm.

See Related Information[21]

Date Posted	June 11, 2014
Recall Status[1]	Open
Recall Number	Z-1782-2014
Recall Event ID	68317[22]
Premarket Notification 510(K) Number	K970492[23]
Product Classification	Cannula, Manipulator/Injector, Uterine[24] - **Product Code** LKF[25]
Product	Cooper Surgical TAMPA CATHETER 5 French 33 cm. Intended for Hysterosonography. Model Number: 61-2005
Code Information	Lot 141525
Recalling Firm/ Manufacturer	CooperSurgical, Inc. 75 Vista Pl Trumbull, Connecticut 06611-3934
Manufacturer Reason for Recall	Sterility of the device may be compromised due to unsealed pouch
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Cooper Surgical Inc notified consignees by letter dated 5/13/14 sent via Federal Express with confirmed delivery receipt. Consignees are requested to return for refund or exchange. If you have any further questions contact the firm at 203.601.5200.
Quantity in Commerce	1180 units
Distribution	Distributed USA (nationwide) including the states of CO, CT, MO, VT, NY, OH, NJ, FL, NC, VA, AL, MA, PA, and CA, and the country of Canada.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = LKF and Original Applicant = ACKRAD LABORATORIES[28]

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