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

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>June 15, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Status</td>
<td>Open</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-1794-2014</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>6837322</td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Code Information</strong></td>
<td>Catalog Number: PM4500; Material Number: M004PM45000; Serial numbers: 16521554, 16538910, 16573588, 16615973, 16744972, 16744973, 16744974, 16744975, 16572127, 10572830. Expiry Dates: May 7, 2014 to January 13, 2017.</td>
</tr>
<tr>
<td><strong>Recalling Firm/Manufacturer</strong></td>
<td>Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-8530</td>
</tr>
<tr>
<td>For Additional Information Contact</td>
<td>Brent Hathcock 510-440-7700</td>
</tr>
<tr>
<td><strong>Manufacturer Reason for Recall</strong></td>
<td>Some units of Intella Tip MiFi XP Temperature Ablation Catheters were not manufactured according to specification.</td>
</tr>
<tr>
<td><strong>Action</strong></td>
<td>Customers were informed of the recall via overnight letter sent on May 15, 2014.</td>
</tr>
<tr>
<td><strong>Quantity in Commerce</strong></td>
<td>968 units - all models</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td>Nationwide Distribution.</td>
</tr>
</tbody>
</table>

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §600.3

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Links on this page:

3. [www.fda.gov/default.htm](http://www.fda.gov/default.htm)
4. [www.fda.gov/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm)
5. [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm)

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

Date Posted: June 16, 2014
Recall Status: Open
Recall Number: Z-1795-2014
Recall Event ID: 6837322

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: 16550404, 16550408, 16573552, 16573563, 16573564, 16596365, 16606148, 16615974, 16615975, 16623756, 16743274, 16743275, 16743276, 16743276, 16757632, 16757633, 16757634, 16757635, 16757636, 16757637, 16757638, 16757639, 16757781, 16757782, 16757783. 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 §7.56.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmN.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=127482
6/23/2014
### Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 8mm x 8F (2.67mm)

**Date Posted:** June 16, 2014

**Recall Status**
Open

**Recall Number**
Z-1796-2014

**Recall Event ID**
6837322

**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: M004PM4500N40; Serial numbers: 16521587, 16515976, 16523754, 16523755, 167356927, 16735658, 16743271, 16872124. Expiry Dates: May 11, 2014 to January 13, 2017

**Recalling Firm/Merchant**
Boston Scientific Corporation
47215 Lakeview Blvd
Fremont, California 94538-8530

**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.

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1. For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §803(f)

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Links on this page:
3. [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)
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6. [scripts/cdrh/devicesatfda/index.cfm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm)
7. [scripts/cdrh/cfdocs/cfPMN/pmM.cfm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm)
8. [scripts/cdrh/cfdocs/cfRL/rl.cfm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm)
10. [scripts/cdrh/cfdocs/cfRES/res.cfm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm)

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

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>June 16, 2014</th>
</tr>
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<tbody>
<tr>
<td>Recall Status</td>
<td>Open</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-1797-2014</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>683732</td>
</tr>
<tr>
<td>Product</td>
<td>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.</td>
</tr>
<tr>
<td>Code Information</td>
<td>Catalog Number: PM4790; Material Number: M004PM47900; Serial numbers: 16538009, 16743272, 16743273, 16872937 Expiry Dates: May 11, 2014 to January 13, 2017</td>
</tr>
<tr>
<td>Recalling Firm/Manufacturer</td>
<td>Boston Scientific Corporation 47215 Lakeview Blvd Fremont, California 94538-6530</td>
</tr>
<tr>
<td>For Additional Information Contact</td>
<td>Brent Hathcock 510-440-7700</td>
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<td>Action</td>
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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.56

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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDETextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm

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

Date Posted: June 16, 2014
Recall Status: Open
Recall Number: Z-1798-2014
Recall Event ID: 683732
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: PM4790CK2; Material Number: M004PM47900K2; Serial numbers: 16739673, 16739674, 16739675, 16739676, 16739677, 16739678, 16739679, 16739680, 16572121, 16973935 Expiry Dates: May 11, 2014 to January 13, 2017

Recalling Firm/Manufacturer: Boston Scientific Corporation, 47215 Lakeview Blvd, Fremont, California 94538-6550

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.

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55.

Links on this page:
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6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMADE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=127485

6/23/2014
Class 2 Recall
IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 8F (2.67mm)

Date Posted: June 16, 2014
Recall Status: Open
Recall Number: Z-1799-2014
Recall Event ID: 9937922

Product: IntellaTip MiFi XP Temperature Ablation Catheter; 10m x 6F (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: M004PM4790N4; Serial numbers: 167432669, 16782007; 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 §7.56

Links on this page:
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8. /scripts/cdrh/cfdocs/cfRL/ri.cfm
9. /scripts/cdrh/cfdocs/cfMAUD/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=127486
6/23/2014
Class 2 Device Recall TAMPA CATHETER 5 French 33 cm.

Date Posted: June 11, 2014
Recall Status: Open
Recall Number: Z-1782-2014
Recall Event ID: 683172
Premarket Notification 510(K) Number: K570492
Product Classification: Cannula, Manipulator/Injector, Uterine, Product Code LKF
Product: Cooper Surgical TAMPA CATHETER 5 French 33 cm. Intended for Hysterosonography. Model Number: 61-2005
Code Information: Lot 141525
Recalling Firm/Manufacturer: Cooper Surgical, Inc.
    75 Vista Pl
    Trumbull, Connecticut 06611-3034
Manufacturer Reason for Recall: Sterility of the device may be compromised due to unsealed pouch
FDA Determined Cause: 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: TPUC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 67.56
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

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm

6/23/2014