Device Master Record	DMR# RTC25C	REV. A	ECO: 2232
	Effective Date: NOV 1 3 2013		
Quality: Doris F Walter 11/13/13		Production: Barbara A Niemeyer 11/13/13	
Engineering: Steven C. Powers 11/13/13		Sales/Mktg: Brenda B Beasley 11/13/13	

RTC 25-C
INLINE AEROSOL TEE ADAPTER

Refer to the following Drawings:

RTC25CTD	Molded RTC 25-CT Adapter Tee Specification
RTC25CCD	Molded RTC 25-CC Adapter Cap Specification
RTC25CID	Molded RTC 25-CI Adapter Insert Specification
RTC25CA	Assembled RTC 25-C Inline Aerosol Tee Adapter Specification

Refer to the following Device History Records:

RTC25CA	Assembled RTC 25-C Inline Aerosol Tee Adapter Specification
RTC25CP	Packaged RTC 25-C Inline Aerosol Tee Adapter Specification

Refer to the following Incoming Inspection: N/A

Refer to the following CNC Program: N/A

Refer to the following Quality Inspection Record: N/A

Refer to the following Package Insert:

RTC 25-C Instructions RTC 25-C Package Insert

Packaging:

For Samples: 1 (One) part per 5 x 6 heat-sealed poly bag
RTC 25-C Package Insert
Identification Label

For 25's: 25 (Twenty-five) single-packaged parts per 12 x 12 ziplock bag
RTC 25-C Package Insert
Identification Label

For 50's: 50 (Fifty) single-packaged parts per 12 x 15 ziplock bag
RTC 25-C Package Insert
Identification Label

Further processed in: N/A

Regulatory Status: Exempt per 21CFR 868.5240

Health Canada Device License Number: N/A

Device History Record	DHR# RTC25CA	Rev. A	ECO: 2232
Category: **Assembly**	Effective Date:	NOV 1 3 2013	
Quality: Doris F Salter 11/13/13		Production: Barbara A Niemeyer 11/13/13	
Engineering: Steven C. Reiner 11/13/13		Sales/Mktg: Mark B Klasing 11/13/13	

RTC 25-C
INLINE AEROSOL TEE ADAPTER

Job #: _____ Quantity Scheduled: _____ Date: _____

Drawings Needed:

RTC25CTD	Rev. θ	Molded RTC 25-CT Adapter Tee Specification
RTC25CCD	Rev. θ	Molded RTC 25-CC Adapter Cap Specification
RTC25CID	Rev. θ	Molded RTC 25-CI Adapter Insert Specification
RTC25CA	Rev. θ	Assembled RTC 25-C Inline Aerosol Tee Adapter Spec.

Procedure:

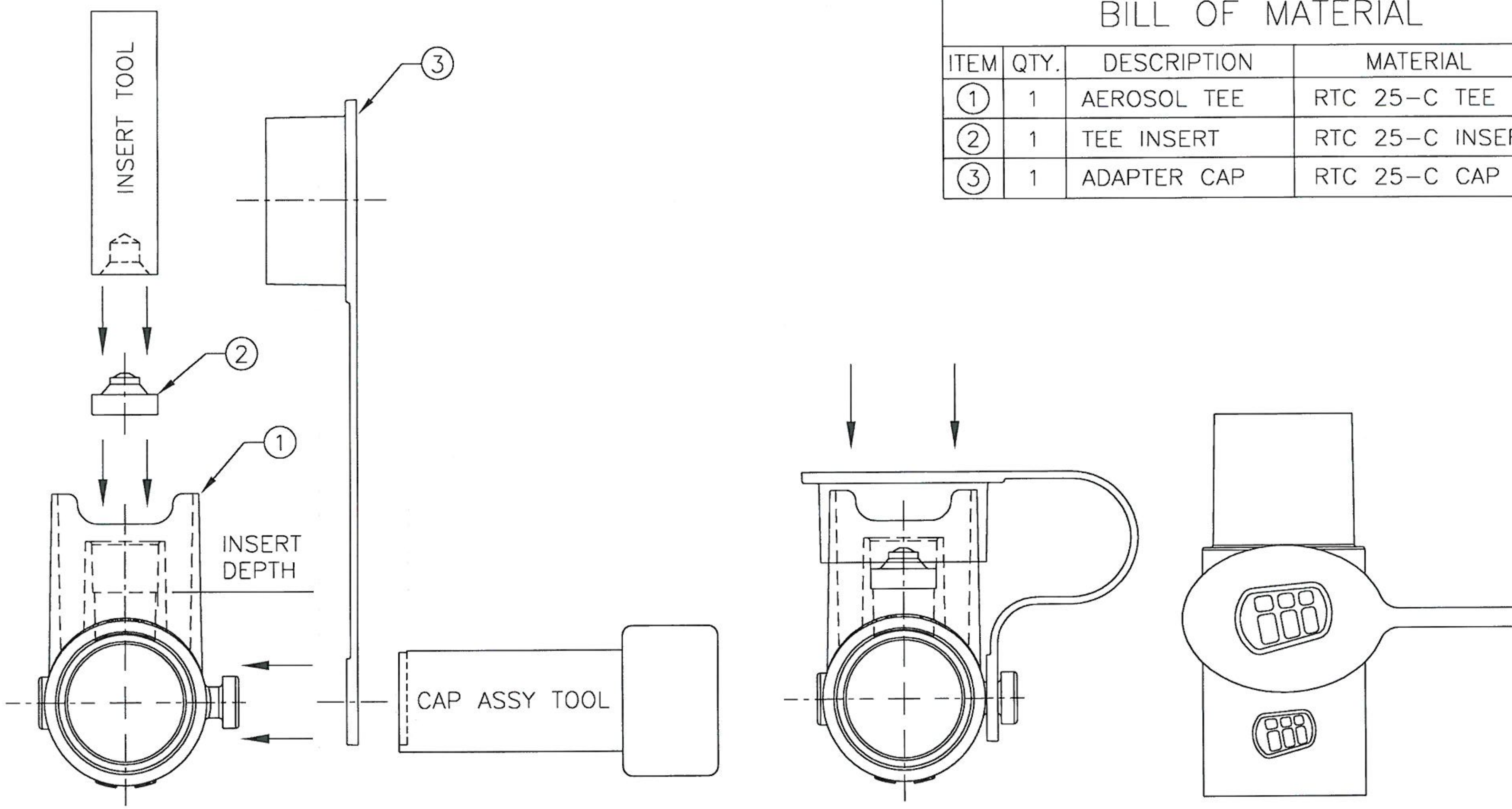
1. Sign in molded RTC 25-C parts in the space provided below. Note that if any extra parts need to be signed in during the assembly process, sign them in on the DHR sheet.
2. Trim gate areas flush and remove excess flash from molded components, if necessary. Visually inspect and blow out with dry, compressed air. Record number of rejected parts.
3. Assemble devices per drawing RTC25CA. DO NOT REMOVE INSERTS ONCE FULLY INSERTED.
4. Visually inspect Tee Assembly to verify that Insert is completely seated. Use Insert assembly tool to completely seat the insert, if necessary.
5. Obtain hand count of parts. Record total quantity of accepted and rejected parts.
6. Assembly Supervisor or Designee: Inspect 10% (but not more than 50) of the lot per drawing RTC25CA.
7. Quality Control: Review DHR for completeness and accuracy.
8. Quality Control: Sample Size: per ANSI/ASQ Z1.4 Single sampling plan for normal inspection – General Inspection Level III. Inspect per drawing RTC25CA (AQL 2.5). Verify that insert is seated completely against internal tee ledge.
9. Sign RTC 25-C Tee adapters into inventory or out to packaging.

Parts Sign-in:

Material	Drawing	Qty	III Lot or Job#	Initials	Date
Molded RTC 25-CT Adapter Tee	RTC25CTD				
Molded RTC 25-CC Adapter Cap	RTC25CCD				
Molded RTC 25-CI Adapter Insert	RTC25CID				

BILL OF MATERIAL

ITEM	QTY.	DESCRIPTION	MATERIAL
(1)	1	AEROSOL TEE	RTC 25-C TEE
(2)	1	TEE INSERT	RTC 25-C INSERT
(3)	1	ADAPTER CAP	RTC 25-C CAP



ASSEMBLY:

1. USING INSERT TOOL, FIRMLY PRESS THE TEE INSERT INTO THE CENTER TEE PORT TO THE DEPTH SHOWN. FIT MUST BE VERY SNUG.
2. WITH CAP ORIENTED AS SHOWN, PRESS CAP'S TETHER RING INTO CAP ASSEMBLY TOOL.
3. PUSH THE CAP'S TETHER RING ONTO THE EAR OF THE TEE WITH CAP ASSEMBLY TOOL.
4. PRESS THE CAP ONTO THE ELLIPTICAL CENTER PORT OF THE TEE.

REV.	BY	ECO #	DATE
⊖	SCR	2187	4-22-13

NAME: RTC25CA
TYP: ASM SCALE: 1X
TOLERANCES UNLESS OTHERWISE SPECIFIED
.X=±.1
.XX=±.01 .XXX=±.005

APPROVALS
Steven C. Reiner 9/27/13
Doris F Zalter 9/30/13
[signature] 9/27/13
[signature] 9/30/13

INSTRUMENTATION INDUSTRIES, INC.
2990 Industrial Blvd. Bethel Park, PA 15102

TITLE: RTC 25-C
INLINE AEROSOL TEE ASSEMBLY

Device History Record	DHR# RTC25CP	REV. A	ECO 2232
Category: **Packaging**	Effective Date: NOV 1 3 2013		
Quality: 11/13/13	Production: 11/13/13		
Engineering: 11/13/13	Sales/Mktg: 11/13/13		

RTC 25-C

INLINE AEROSOL TEE ADAPTER

Job #: _____ Quantity Scheduled: _____ Date: _____

Package Insert Needed:

RTC 25-C Instructions rev. A RTC 25-C Package Insert

Procedure:

1. Sign in inspected RTC 25-C Tee Adapters.
2. Packaging:
   a. For Samples: Single package in 5 x 6 heat-sealed poly bag with package insert. Have 1st Package check performed after the first sample is bagged.
   b. For 25's: Single package in 4 x 5 or 5 x 6 heat-sealed poly bag without package insert. Place 25 single-packaged parts and a package insert into each 12 x 12 ziplock bag. Have 1st Package check performed after the first 25-pack is bagged.
   c. For 50's: Single package in 4 x 5 or 5 x 6 heat-sealed poly bag without package insert. Place 50 single-packaged parts and a package insert into each 12 x 15 ziplock bag. Have 1st Package check performed after the first 50-pack is bagged.
3. 1st Package check (other than by original packager): Verify that the correct package insert is included in the bag.
4. Obtain count on packages to determine number of labels needed.
5. Forward DHR to QC for review and label requisition.
6. Quality Control: Generate number of labels needed (plus one additional label to attach to DHR as a proof). Record number of labels generated.
7. Quality Control: Proof label by comparing to the example below. Attach extra label to DHR.

Not Sterile
RTC 25-C Inline Aerosol Tee Adapter f/Single Patient Reuse
LOT#: PXXXXXXX QTY: 1, 25, or 50
MFG BY- Instrumentation Industries, Inc.
2990 Industrial Blvd., Bethel Park, PA 15102
Customer Service 1-800-633-8577

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8. Return DHR and required number of labels to packaging.

9. Apply 1 (one) label to each package.
10. Return DHR to QC.
11. Quality Control: Review DHR for completeness and accuracy.
12. Quality Control: Inspect packaging and labeling.
13. Release packaged RTC 25-C Tee Adapters for shipment.